

REMARKS

I. Status of the Claims

Claims 24, 25, and 28-39 are pending in this application. Claim 29 has been amended to provide proper antecedent basis. No new matter has been introduced by this amendment, nor is any additional search by the Office thereby necessitated.

Applicants acknowledge and appreciate the Examiner's withdrawal of the 35 U.S.C. §§ 102 and 103 rejections over, respectively, *Jackman* and *Gans/Jackman*. (Office Action, page 2.)

II. Rejection Under 35 U.S.C. § 112, Second Paragraph

Claim 29 stands rejected as allegedly lacking sufficient antecedent basis for the recitation of "the alkanoic acid or alkenoic acid." (Office Action, pages 2-3.) Applicants have amended claim 29 to depend from claim 28 instead of from claim 24. Claim 28 recites the terms alkanoic acid and alkenoic acid and, thus, provides an antecedent basis for claim 29. Accordingly, Applicants respectfully request withdrawal of this rejection.

III. Rejection Under 35 U.S.C. § 103(a)

Claims 24, 25, 28, and 30-39 stand rejected as unpatentable under 35 U.S.C. § 103(a) over the combination of International Publication No. 96/13249 to Sandoz Ltd. ("*Sandoz*") and European Patent Application No. EP 0 273 202 A2 to Van Scott et al. ("*Van Scott*"). The Examiner alleges that it would have been obvious to use organic acids as permeation enhancers in the composition of *Sandoz* in view of

Van Scott's disclosure of using hydroxyacids as enhancers in topical compositions. (Office Action, pages 3-4.) Applicants respectfully traverse this rejection for at least the following reasons.

To establish a *prima facie* case of obviousness there must be a suggestion or motivation to combine the reference teachings. M.P.E.P. § 2143. The Examiner must show some teaching, suggestion or motivation supporting the combination of reference teachings. *In re Geiger*, 815 F.2d 686, 688 (Fed. Cir. 1987) (citation omitted). "The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination." M.P.E.P. § 2143.01 (emphasis in original and emphasis supplied). Here, there is no motivation to make the proposed combination.

The Examiner identifies a deficiency of *Sandoz* as teaching organic acids, but not as permeation modulators. (Office Action, page 3, lines 20-21.) The Examiner attempts to correct this deficiency by relying on *Van Scott* for the proposition that hydroxyacids can be used in therapeutic compositions to enhance the topical action of topical agents. Specifically, the Examiner proposes that it would have been obvious to substitute the organic acids of *Sandoz*, which are used as preservatives and emulsifiers, with the hydroxyacids of *Van Scott*, presumably because hydroxyacids are organic acids. There is, however, no hint or suggestion in the cited references to substitute the hydroxyacids of *Van Scott* for the preservatives and emulsifiers of *Sandoz*.

Sandoz discloses suitable emulsifiers useful in its compositions, including in the list only one organic acid, stearic acid. (*Sandoz*, pages 6-8.) The only other particular organic acid mentioned in *Sandoz* is sorbic acid, which is mentioned for its preservative

characteristics. (*Sandoz*, pages 8-9.) *Van Scott*, on the other hand, is relied upon for its teaching of hydroxyacids as topical agent activity enhancers. But neither stearic acid nor sorbic acid is a hydroxyacid. And although hydroxyacids, stearic acid, and sorbic acid fit only very generically into the category of organic acids, the Examiner has not shown how there would be any motivation to substitute either sorbic acid or stearic acid for any hydroxyacid in the composition of *Sandoz*. Accordingly, the Examiner has not provided clear and particular evidence that it would have been obvious to one of ordinary skill in the art to have made the proposed substitution. Therefore, as no *prima facie* case of obviousness has been established, Applicants respectfully request withdrawal of this rejection.

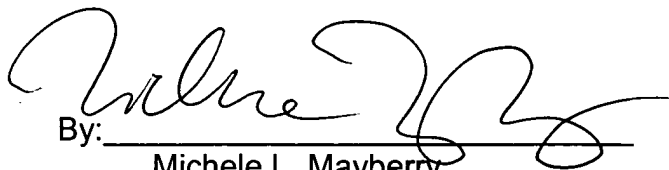
IV. Conclusion

In view of the foregoing amendment and remarks, Applicants respectfully request the reconsideration and reexamination of this application and the timely allowance of the pending claims.

Please grant any extensions of time required to enter this response and charge any additional required fees to our Deposit Account No. 06-0916.

Respectfully submitted,

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Attachment: Appendix

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APPENDIX TO AMENDMENT

VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE CLAIMS:

Please amend claim 29 as follows:

29. (Once Amended) The formulation of claim **24 28** wherein the alkanoic acid or alkenic acid is capric acid, octanoic acid or oleic acid.